REMARKS

This paper is responsive to the Office Action dated May 24, 2004. Claims 1, 2 and 7 are pending in this application and have been rejected. Applicant respectfully requests reexamination in light of the remarks which follow.

Claim Rejection - 35 USC § 101

In this rejection, the Examiner states that there are two membranes in the apparatus (page 2, line 10). Applicant respectfully asserts that claim 1 never included two membranes. Claim 1 included an indicator portion and a gas permeable membrane and a container. The container has a medium portion and an indicator portion which is sealed from the medium portion by the membrane. Clause (b) of claim 1 is separated from clause (a) by a semicolon. Therefore, the language ", which permeates CO_2" can only refer to the preceding CO_2 gas permeable membrane, not the container which is in clause (a). The medium portion and indicator portion of the container refer to the two volumes (5a) and (6a) of Figure 1, not CO_2 gas permeable walls.

Further more, since the claim contains no other membrane, but in fact has a separate container recited up in clause (a), the "which" permeates CO_2 gas clause could have and only did refer to the gas-permeable membrane.

If the Examiner would construe the word "container" to mean membrane, this does not comport with the clear wording of the claim, or the specification which supports and explains it. The container referred to by Applicant is shown in Figure 1A which is labeled (3a). This is the outside envelope. The indicator portion (6a) is at the bottom which is a region surrounded by the bottom portion of container (3a) and the membrane (4a).

Next, the Examiner states if the microorganisms do not generate sufficient CO_2 to maintain the microorganisms, the membrane would have no way of providing CO_2 to the microorganisms. The Examiner is respectfully requested to refer to Applicant's specification, page 4, beginning at line 5 which states:

> . . .the CO_2 gas given off by the process of microbial growth build up pressure until reaching to the threshold level so that only excess amounts of CO_2 gas permeate the membrane and react on a color-tuning CO_2 indicator.

This describes the initial CO_2 gas generation in the microbial area which generate CO_2 to maintain the organisms. The membrane provides CO_2 not to the microorganisms, but to the indicator. The microorganisms of cells generate the CO_2 within the culture medium portion. Applicant's specification states that the purpose of membrane is to maintain a level of CO_2 density inside the culture medium portion. And that this is need for detection of certain microorganisms listed at page 4, ,lines 2 and 3.

Detection is not the same as initial generation of CO_2. CO_2 is initially generated, pressure builds up and then where there is sufficient pressure, there can be detection. In his last sentence, at page two The Examiner states:

> If the microorganisms do not generate sufficient CO_2 to maintain the microorganisms, the membrane would have no way of providing $CO_2$to the microorganisms.

First, the Examiner should note that the microorganisms do in fact generate CO_2 as stated at the top of page 4. Next, in the Examiner's statement the Examiner refers to "membrane", but does not specify which membrane he refers to. Does the Examiner refer to the "container" membrane or to the membrane which contains the indicator only which is permeable to CO_2".

Prior Art Rejections

Claim 1

Applicant has claimed a method which includes a unique CO_2 gas permeable membrane which maintains a level of CO_2 gas in the medium portion. This concept is totally lacking from '060 which has only a sensor (2), which cannot function as Applicant's claimed membrane. The sensor of '060 is simply not another fluid which can absorb carbon dioxide. The sensor is fixed to the membrane. The only use of carbon dioxide by the sensor is that used in its chemical reactions. On the other hand, Applicant now claims a membrane which controls CO_2 within the medium.

Similarly, the sensor in '769 which is a patent issued to the same patentees and to the same company as '060 is the same sensor.

The Examiner's Position

At the top of page 3, the Examiner stats that the previous rejections are maintained. This case is an RCE with a new limitation in claim 1. This limitation was never examined and for this reason the prior rejection cannot be maintained.

The Examiner in stating his position and citation of additional features from the art, such as membrane material and specific microbes has never articulated a rejection based upon these "observations". Applicant should receive a rejection which states how the references teach and suggest the claimed invention, see In re Sernaker 217 USPQ 1. A mere listing of elements found in the art does not show how these teach Applicant's claimed invention. The previous rejection does not discuss these new elements.

At the top of page 3 the Examiner has stated that the rejections of claim 1 under 35 USC § 102(b) over Turner and the rejection of claim 1 under 35 USC § 102(e) over DiGuiseppi and the rejection of claims 2 and 7 under 35 USC § 103(a) over each Turner and DiGuiseppi are maintained. This statement is not understood because Applicant has filed an amendment after final rejection on March 29, 2004. In this amendment, Applicant amended the claims to state that there is a fluid indicator portion. I that amendment Applicant further argued the fluid indicator is now

clearly claimed. In the rejection dated January 29, 2004, the term in the claim was "mobile", and the Examiner never addressed the question of fluid.

In the rejection dated September 9, 2003, the Examiner rejected the claims (claim 1) as being anticipated by DiGuiseppi. However, in the amendment dated April 4, 2003, Applicant amended the claim to state that there was a fluid indicator isolated from the medium portion. The Examiner in the rejection did not discuss the term "fluid indicator" in claim 1. In that Office Action (September 9, 2003), the Examiner did reject claims 2 and 7 under 35 USC § 103(a) as being unpatentable over Turner and DiGuiseppi. The Examiner concedes in that Office Action, at page 5, lines 3 and 4 that the references do not state indicator state. This previous rejection by the Examiner shows that claim 1 with the fluid indicator could not possibly have been rejected under 35 USC § 102 because the indicator state as conceded by the Examiner was not shown. Therefore, the previous Office Actions do not support a rejection under 35 USC § 102 of claim 1. Still further, they do not support rejections under 35 USC § 103 because the claims as now amended call for the fluid indicator in both clauses (a) and (b) of claim 1 and claim 2.

Beginning at line 8 of page 3, the Examiner has stated his position with respect to this rejection. The Examiner asserts that the membrane of the present invention cannot control CO_2 within the medium. The Examiner is respectfully requested to refer to clause (b) of the claim which requires that the gas-

permeable membrane permeates CO_2 gas at a pressure of a microorganism. This is a function of the membrane, and is described at pages 3 and 4 of Applicant's specification. It is simply a membrane which requires a certain pressure level in order to pass CO_2. The Examiner has not discussed the pressure limitation in the claim at all.

The Examiner correctly observes that the only possible source of CO_2 within the sealed container would be the microorganisms. Applicant observes that these are the microorganisms of the fluid culture medium which grow and create CO_2.

Next the Examiner argues that the CO_2 generated by the microorganisms would pass through the permeable membrane to the indicator which would then indicate the presence of CO_2. This does not comport with the claim which requires that the permeation be at a pressure required to maintain a density of CO_2.

Next, the Examiner argues that it is not seen that any CO_2 would pass from the indicator to the microorganisms from any source. This is simply not the case. The CO_2 according to the claim is that which permeates the gas permeable membrane at a pressure required to maintain a density of CO_2 level. If the Examiner is referring to his observation at page 2 that there are "two membranes, one of which would include the container" then Applicant agrees that CO_2 does not pass through the container wall. In fact, the container wall as Applicant has pointed out above is not even a membrane. Certainly CO_2 does not pass from any source through the container wall.

Next, the Examiner states if a significant amount of CO_2 pass from the indicator to the microorganisms, the indicator would not signal an amount of CO_2 is present. This observation by the Examiner is not related to the claims or Applicant's specification. Applicant does not teach that CO_2 passes from the indicator to the microorganisms. Nor does Applicant claim that there is a relationship which allows CO_2 to pass to the microorganisms from the indicator. On the other hand, even in the prior art, such as '060, if CO_2 were passing from the indicator back to the microorganism culture medium, and inaccurate signal of CO_2 would occur. However, the indicator of the prior art is not a fluid, instead it is fixed on a membrane. Once there is a reaction with the indicator, the CO_2 is combined with indicator and the CO_2 level changes.

Next, the Examiner states if a significant amount of CO_2 did not pass through the membrane to the indicator, the indicator would not signal an accurate amount of CO_2 is present. This is correct, but is simply not related to Applicant's claim, or Applicant's description of how things work at pages 3 and 4.

Finally, the Examiner argues, "further the materials from which the permeable membrane is made as disclosed in the specification as originally filed are the same materials from which the permeable membranes are made in the references cited herein. The references show that the membrane of '060 is nylon, and that the membranes in '769, as disclosed in column 7, are uncured polymers, such as silicone, silicone polymers, etc.

Applicant respectfully submits that the membranes disclosed in the references are not those discussed by Applicant at page 3 of Applicant's specification. Still further, the membranes disclosed are not those which perform as Applicant's sets forth in clause (b) of claim 1. Applicant states that the CO_2 gas-permeable membrane permeates gas at a pressure required to maintain a density of CO_2 gas at a level required for growth of a microorganism. This is not disclosed in any of the references. The Examiner has not stated how the pressure of these membranes in the references suggests one which functions like that et forth in claim 1.

Next, the Examiner argues that DiGuiseppi teaches in column 6, lines 44 - 49 that the semipermeable membrane may be adjacent to the specimen and growth medium to form an integral membrane. The Examiner states how this renders Applicant's claim obvious. For this reason any rejection based upon this statement is now understood. There is no reasoning in this rejection which shows how this statement teaches or suggests the claimed invention.

Next, the Examiner states in column 8, last full paragraph, oxygen may be provided by a gas-permeable membrane and anaerobic microorganisms may be determined. First, Applicant notes that oxygen provision by a gas is not claimed. Next, column 8 of DiGuiseppi '769 relates to a rotary culture apparatus and the word "oxygen" does not appear. Therefore, this statement by the Examiner does not show any teaching or suggestion in the reference of Applicant's claimed invention.

At the top of page 4, the Examiner cites Turner, column 1, Table 7, as listing N. meningitidis which is disclosed in the present specification as requiring CO_2 to be detected. First, Applicant discloses than claims that there are two separate fluids, the fluid culture medium and the fluid indicator portion. On the other hand, '060 does not have a fluid indicator portion. It has an indicated membrane which immobilizes on or within it a sensor. The immobile sensor clearly cannot be fluid as Applicant claims. Next, '060 places the sensor in the culture bottle. In short, the culture bottle in '060 will retain the CO_2 and not transfer CO_2 to a fluid indicator portion as does Applicant. The only transfer in '060 is directly to the indicator medium immobilized on or within the nylon sensor membrane. Therefore, '060 could conceivably detect N. meningitidis with CO_2 levels rising in the container. However, '060 does not have the fluid indicator portion which would otherwise reduce the CO_2 levels in the fluid culture medium.

The Examiner never states why the detection of N meningitidis by one apparatus teaches or suggests Applicant's claimed method which a membrane which maintains a level of CO_2 in the culture medium.

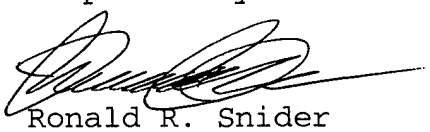
Claim 7

In the previous rejections of claim 7, the Examiner has not addressed element (f) which is the identification of initial quantities of microorganisms obtained by comparing measured time

against contents of a table which hold precollected time data on each microorganism species of known initial quantities in known amount of sample. The Examiner merely argues that this would be obvious at page 5 of the Office Action dated September 9, 2004 without any citation to those portions of the reference relied upon which would teach or suggest such a step. The Examiner refers only to "minimum amounts of microorganisms detectable are discussed". This, Applicant respectfully submits, is not a teaching of element (f) of claim 7.

In view of the foregoing, it is respectfully submitted that the application is now in condition for allowance, and early action in accordance thereof is requested. In the event there is any reason why the application cannot be allowed in this current condition, it is respectfully requested that the Examiner contact the undersigned at the number listed below to resolve any problems by Interview or Examiner's Amendment.

Respectfully submitted,



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